

EXHIBIT 2

Linda A. Motyka, Ph.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

IN RE DEPAKOTE CASES:

RHEALYN ALEXANDER, et al.,

Plaintiffs,

VS.

CASE NUMBER
12-CV-52-NJR-SCW

ABBOTT LABORATORIES, INC., et al.,

Defendants.

Case affected:

A.S., a minor, by MARTHEE
SANSONE, individually and as
parent and next friend of A.S.

VS.

CASE NUMBER
17-CV-793

ABBOTT LABORATORIES, INC.

DEPOSITION OF LINDA A. MOTYKA, Ph.D.

The deposition of Linda A. Motyka, Ph.D., was taken at the law office of Heninger, Garrison & Davis, in Birmingham, Alabama, on November 6, 2017, commencing at 9:00 a.m., before Mitzi Smith, Court Reporter & Notary Public as Commissioner, pursuant to the stipulations set forth herein.

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1 A With the attorneys?

2 Q Yes.

3 A No.

4 Q In your work in the Paxil litigation,
5 did you review the Paxil IND?

6 A Yes.

7 Q Did you review the Paxil NDA?

8 A Parts of it, yes.

9 Q Did you review correspondence between
10 GFK and FDA?

11 A Yes.

12 Q Why did you review correspondence from
13 the GFK and FDA?

14 A Let me think. Because it was provided
15 to me.

16 Q Did you rely upon the correspondence at
17 least in part in reaching your opinions in
18 those cases?

19 MR. GARRISON: Object to the form.

20 A Maybe.

21 Q On page 34 of your report, you list
22 documents reviewed/referenced.

23 A Yes.

24 Q Is that list complete in terms of the
25 documents that you've reviewed?

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1 A Whatever's in here in Exhibit 1 as well
2 as what may be referenced in my report.

3 Q Okay. So to the extent it is not listed
4 on Exhibit 1 or referenced in your report, fair
5 to say you haven't looked at it?

6 A Right. I do believe this is complete.

7 Q You haven't looked at any deposition
8 transcript of Abbott Company witnesses;
9 correct?

10 A Correct.

11 Q And you haven't looked at any trial
12 transcripts for any witness in this litigation,
13 have you?

14 A Correct.

15 Q Have you looked at the deposition
16 transcript of any other experts in this
17 litigation?

18 A No.

19 Q I see here on page 36, items 43 and 44
20 are the expert reports of Suzanne Parisian and
21 David Kessler. Do you see that?

22 A Yes.

23 Q Why did you review those reports?

24 A They were given to me.

25 Q Did you ask for them?

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1 my calculation that's about 250 hours total.

2 Do you know how much of that 250 hours was
3 spent reviewing documents versus writing your
4 report? Can you give me even a percentage
5 breakdown?

6 A No.

7 Q On page 32, at the top of page 32, Item
8 4, additional information requested. When did
9 you request this information?

10 A What do you mean?

11 Q Well, when did you request it? Did you
12 request it a week ago, five months ago? When
13 did you request the information?

14 A This is for in September.

15 Q So you just pointed to the front page of
16 your report dated September 26th. So you've
17 requested the information on that date?

18 A Yeah, but that's not for this report. I
19 don't need this information for my report.

20 Q Why do you need this information?

21 A For any future work that the attorneys
22 may have in mind. This is just for my
23 information only.

24 Q As far as you're concerned for the
25 opinions you intend to offer in these cases, it

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1 is not necessary for you to review anything
2 further.

3 A Correct.

4 Q The third bullet here says all
5 correspondence between Abbott and FDA on
6 Depakote and birth defects. We talked just a
7 minute ago I think about the fact that you got
8 a couple of pieces of correspondence from
9 either your search on the website or from FOI
10 services; correct? You mentioned you had a few
11 pieces of correspondence through those two
12 means; right?

13 A And from the drugs at FDA.

14 Q And other than that, you don't have any
15 other correspondence as between Abbott and FDA;
16 right?

17 A Not that I can remember.

18 Q You don't think it's relevant to your
19 opinion to have correspondence between Abbott
20 and FDA on Depakote and birth defects?

21 A For what I've written here, no. I've
22 gotten everything I need from the public
23 domain.

24 Q Did you review the labels for any other
25 anti-epileptic drugs before reaching your

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1 information.

2 Q And other than any scientific
3 publications?

4 A They had scientific publications on
5 their website.

6 Q And other than any scientific
7 publications that were on the NAAED website,
8 did you do any other independent -- did you do
9 any independent search of the scientific
10 literature on Depakote or valproic acid?

11 A Yes, to gain specific documents that I
12 needed, yes.

13 Q So what were those searches?

14 A Those searches would have been for the
15 CDC documents relating to the study in Lyon
16 France, so I went on the Internet to get those
17 specific documents.

18 Q Was that from the CDC website?

19 A No, that would have been a general
20 search.

21 Q But that was general in looking
22 specifically for that data?

23 A Yes, because I was looking for source
24 data.

25 Q Did you ever go on PubMed prior to

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1 reaching your opinions in this case and do a
2 search for Depakote or valproic acid in birth
3 defects?

4 A I know I linked to some PubMed articles
5 that I had gotten through my research here, but
6 I did not specifically go on PubMed and type in
7 valproic acid or Depakote.

8 Q And anything, any scientific articles
9 that you reviewed, any scientific publications
10 that you reviewed are listed in Exhibit 1;
11 correct?

12 A Or in my report.

13 Q Other than what's listed in your report
14 or in Exhibit 1, you didn't look at any other
15 scientific articles on Depakote or valproic
16 acid and birth defects, did you?

17 A I don't believe so. I believe these
18 lists are complete.

19 Q Complete in the sense that they're
20 representative of what you reviewed; correct?

21 A I believe so.

22 Q You haven't reviewed the IND for
23 Depakote, have you? Or any of the Depakote or
24 Depakene, Depacon, have you reviewed any INDs?

25 A Entire INDs?

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1 Q Well, Stephen Hoff is saying that the
2 FDA was -- told him --

3 A Starting from, "Given the studies'
4 inability to establish this correlation, the
5 proposed sentence should not be incorporated
6 into labeling. A similar proposed sentence in
7 the patient information leaflet was removed in
8 the approval letter for January 2006."

9 Q That seems to indicate two different
10 statements; right? One the labeling and one on
11 the patient information leaflet; correct?

12 A Yes.

13 Q They're removing both.

14 A Yes.

15 Q Okay. I'm going to show you what we're
16 marking as Exhibit 20.

17 (Defendant's Exhibit 19 was
18 marked for identification.)

19 Q And this is a May, 21st, 2000 submission
20 from Abbott to the FDA.

21 A I didn't get a 19. Is that okay?

22 Q No, you're right. That's actually -- 19
23 is a May 21st, 2007 submission from Abbott to
24 FDA entitled Request For Advice Regarding
25 Developmental Delay Labeling for Depakote. Do

1 you see that?

2 A Yes.

3 Q And if we just look at the first
4 paragraph, Stephen Hoff says, "Abbott
5 Laboratories previously submitted a labeling
6 change dated April 18th, 2005 for Depakote to
7 include revised information related to
8 developmental delay in the warnings, usage in
9 pregnancy and the patient information leaflet
10 sections. The agency responded to the proposed
11 labeling by email on February 7th, 2006 that
12 the labeling for developmental delay should not
13 be included." And then he repeats the email,
14 and those are the last two documents we looked
15 at, the April '05 submission and the February
16 2006 email; right?

17 A Yeah.

18 Q Okay. Then you will see under that
19 paragraph it says, "Abbott responded by
20 removing the proposed wording and subsequently
21 the labeling revision was approved on October
22 13th, 2006 without the developmental delay
23 language." You see that?

24 A Yes.

25 Q Okay. Abbott goes on to state that

1 it's, "Continued to monitor the literature and
2 our spontaneous adverse event database for
3 developmental delay associated with valproic
4 acid. We provides an updated analysis of the
5 occurrence of developmental delay in attached
6 white paper which now includes more compelling
7 data from the neurodevelopmental effects of
8 anti-epileptic drug NEAD study. The interim
9 results from the NEAD study are the first data
10 with adequate control from internal IQ using a
11 standard IQ measure and show a significant
12 developmental delay in 185 two year old
13 children exposed to valproic acid during
14 pregnancy." Then if you read further, it says,
15 "Abbott requested the agency review the
16 attached information for the NEAD study and
17 provide advice on the acceptability of these
18 data for use in revised labeling to include
19 developmental delay." And they repeat that
20 statement that they tried to include in 2005.

21 Do you see that?

22 A Yes.

23 Q If you flip over one page, you will see
24 another white paper.

25 A Yes.

1 Q On neurodevelopmental delay.

2 A Uh-huh.

3 Q And again there are -- there is a
4 discussion, and you're welcome to read it, that
5 takes place over until page 6 on the published
6 literature, and on page 6 then continues with
7 Abbott's analysis of its postmarketing
8 database. Do you see that?

9 A Okay. There's a summary here of
10 literature information postmarketing database.

11 Q And if you look at page P2.

12 A I want to read this. Okay. Where are
13 you now?

14 Q P2 on the white paper. And in the
15 middle of that paragraph above clinical studies
16 and case reports, it says, "Given the pattern
17 of findings in this emerging literature in an
18 abundance of caution, Abbott is requesting
19 advice regarding whether it is now appropriate
20 to add language to the current label regarding
21 the potential risk of NDD, neurodevelopmental
22 delay in offspring exposed in utero to
23 valproate. It is hoped that providing this
24 information can better inform the physician and
25 patient in their risk/benefit analysis of

1 appropriate medication use and encourage early
2 intervention when developmental delays do
3 occur." Do you see that?

4 A Yes.

5 Q And so Abbott is again asking in May of
6 2007 to add developmental delay information to
7 its label; right?

8 A Right, but they didn't need to ask.
9 They could have done it. It says here in the
10 back, if you look in the back here, it talks
11 about previous contact with the FDA page 8, and
12 it says that they convened an expert panel of
13 advisors in January 2005 to provide advice on
14 scientific and clinical meaning of the emerging
15 literature. It was not necessary for them to
16 ask before they put information in the
17 labeling.

18 Q Dr. Motyka, you've seen certainly in
19 response to -- they made a proposal in April of
20 2005, and that proposal was rejected; correct?

21 A Yes.

22 Q Okay. And now they're asking again in
23 May of 2007, they're making that same proposal.
24 Are you aware of the FDA's response to this
25 submission?

1 A Yes.

2 Q Other than that has two, you have not
3 read a single published article on the
4 comparative risk of Depakote; correct?

5 A Correct. I did not read them. I relied
6 on the summary.

7 (Defendant's Exhibit No. 26 was
8 marked for identification.)

9 Q I'm going to show you what we're going
10 to mark as Exhibit 26. And I just have one
11 question for you, Doctor, and that's whether or
12 not you've ever seen this study before.

13 A Not that I recall.

14 (Defendant's Exhibit No. 27 was
15 marked for identification.)

16 Q Okay. I'll show you what we're going to
17 mark as Exhibit 27 and ask if you've ever seen
18 this study before.

19 A Not that I recall, no.

20 (Defendant's Exhibit No. 28 was
21 marked for identification.)

22 Q I show you what we're marking as Exhibit
23 28. And actually for the record, Exhibit 26 is
24 an article by Dravet et al in the Journal of
25 Neurology dated April, 1992. Exhibit 27 is an

1 article by Kaneko et al also in the Journal of
2 Neurology in April, 1992. And Exhibit 28 is an
3 article by Kaneko et al and CNS drugs, 1995.

4 Have you seen this article before?

5 A 28?

6 Q Yes.

7 A I don't believe so, no.

8 (Defendant's Exhibit No. 29 was
9 marked for identification.)

10 Q Exhibit 29 is an article by Lindhout and
11 Omtzigt in Epilepsia 1994. Have you seen this
12 article before, Doctor?

13 A I don't recall it.

14 (Defendant's Exhibit No. 30 was
15 marked for identification.)

16 Q Exhibit 30 is an article by Samren et al
17 in the Journal of Epilepsia dated 1997. Have
18 you seen this article before, Doctor?

19 A Not that I recall.

20 (Defendant's Exhibit No. 31 was
21 marked for identification.)

22 Q Exhibit 31 is a practice parameter
23 published in Epilepsia entitled Management
24 Issues For Women With Epilepsy. Ask you if
25 you've seen this practice parameter before.

1 before?

2 A I don't recall it, no.

3 (Defendant's Exhibit No. 35 was
4 marked for identification.)

5 Q Exhibit 35 is an article entitled
6 Neurodevelopmental Effects of Anti-Epileptic
7 Drugs By Dr. Meador published in 2002 in
8 epilepsy. Have you seen this before?

9 A I don't recall this, no.

10 Q If you turn with me to page 375.

11 A Of this one?

12 Q Uh-huh. Yes.

13 A Yeah.

14 Q On the right-hand column -- excuse me.
15 On the left-hand column in the middle of the
16 page, the third full paragraph says, "The
17 greatest controversy and most critical
18 unanswered question is whether differential AED
19 effects exist." Do you see that?

20 A Yes.

21 Q You have no reason to dispute Dr.
22 Meador's statement published in 2002 about
23 that, do you, Doctor?

24 MR. GARRISON: Object to the form.

25 A I don't even know what it relates to

CERTIFICATE

STATE OF ALABAMA

TALLADEGA COUNTY

I, the undersigned, a CSR, RPR, CRR and Notary Public of the State of Alabama at Large, hereby certify that the proceedings in the herein matter were taken at the time and place therein stated; that the proceedings were reported by me, court reporter and disinterested person, and were thereafter transcribed by means of computer-aided transcription; that the foregoing is a complete and true record of said witness.

I further certify that I am not of counsel or attorney for either or any of the parties in the foregoing proceedings and caption named, or in any way interested in the outcome of the cause named in said caption.

IN WITNESS WHEREOF set my hand and affixed my seal this 16th day of November, 2017.

Mitzi Smith, ACCR# 117, RPR, CRR
Notary Public State of Alabama

My Commission Expires: August 16, 2018